E-FILED on <u>6/1/10</u>

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN JOSE DIVISION

THE CENTRAL INSTITUTE FOR EXPERIMENTAL ANIMALS, a Japanese corporation,

Plaintiff,

v.

THE JACKSON LABORATORY, a Maine corporation,

Defendant.

No. C-08-05568 RMW

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

[Re Docket No. 164]

Defendant, the Jackson Laboratory ("Jackson"), moves for summary judgment that its accused NSG mouse does not infringe plaintiff, the Central Institute for Experimental Animals ("CIEA"),'s asserted patent, either literally or under the doctrine of equivalents. For the reasons set forth below, the court grants the motion for summary judgment of non-infringement.

I. BACKGROUND

CIEA is a non-profit Japanese corporation that develops animal models used for scientific research. Jackson is an independent nonprofit research institution and the world's largest repository of research mice. On December 12, 2008, CIEA filed a complaint against Jackson, alleging patent and trademark infringement and unfair competition. CIEA asserts that a particular type of immunodeficient mouse produced by Jackson, called the NSG mouse, infringes United States Patent ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT—No. C-08-05568 RMW CCL

No. 7,145,055 ("'055 Patent"). The '055 Patent claims a method of producing an immunodeficient mouse by backcrossing two strains of mice as well as the mouse produced by this method and the use of the mouse. The method claimed in the '055 Patent involves backcrossing¹ a NOD/Shi mouse with a C.B.-17-scid mouse to create a NOD/Shi-scid mouse and then backcrossing the NOD/Shi-scid mouse with an interleukin 2 receptor γ chain gene knockout mouse ("IL-2Rγ KO mouse"). *See* '055 Patent 35:10-22.

Following a tutorial and claim construction hearing, the court construed the term "NOD/Shi mouse" to mean a non-obese diabetic mouse that: (1) has not been reproductively separated from the NOD mouse colony created by Dr. Susumu Makino at Shionogi Research Laboratories or (2) has been reproductively separated from that colony by 20 or fewer generations. Dkt. No. 145 at 14. The court construed "NOD/Shi-scid mouse" to mean a mouse strain produced by multiple backcross generations of a C.B.-17 scid mouse with a NOD/Shi mouse. *Id*.

It is undisputed that Jackson's NSG mouse is created by backcrossing a NOD/LtSz-scid mouse. Because NOD/LtSz-scid mice are produced from NOD/LtSz mice, which have been reproductively separated from Dr. Makino's NOD mouse colony for over 20 generations, a NOD/LtSz-scid mouse is not a NOD/Shi-scid mouse. Accordingly, CIEA concedes that under the court's claim construction Jackson's NSG mouse does not literally infringe the '055 Patent. Dkt. No. 153 ¶ 4. The parties dispute whether Jackson's NSG mouse infringes the '055 Patent under the doctrine of equivalents.

II. ANALYSIS

CIEA seeks to claim infringement under the doctrine of equivalents based on its contention that use of the NOD/LtSz-scid mouse is equivalent to use of the NOD/Shi-scid mouse in the context of the invention. Jackson argues that CIEA is barred from asserting infringement under this theory because: (1) the '055 Patent discloses but fails to claim use of NOD/LtSz-scid mice, and (2) adopting CIEA's position that any substrain of NOD mice are equivalent to the NOD/Shi mice would vitiate the NOD/Shi and NOD/Shi-scid claim limitation in its entirety.

¹ Backcrossing is a process of mating two animals so that the offspring have a genetic identity that is closer to the genetic identity of a selected parent.

A. The Disclosure-Dedication Rule

When a patent discloses but does not claim subject matter, the unclaimed subject matter is dedicated to the public and cannot be recaptured under the doctrine of equivalents. *See Johnson* & *Johnston Assocs., Inc. v. R.E. Serv. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). This rule, which is referred to as the disclosure-dedication rule, is based on the fundamental principle that the claims define and give notice of the scope of patent protection. *Id.* at 1052. What is claimed is protected, and "what is not claimed is public property." *Id.* at 1053 (quoting *Mahn v. Harwood*, 112 U.S. 354, 361 (1884)). Because the claims, not the specification, are the sole measure of the patentee's right to exclude, the disclosure of unclaimed subject matter in the specification "has made it public property if it was not so before." *Id.* Permitting recapture of this subject matter under the doctrine of equivalents would "conflict with the primacy of the claims in defining the scope of the patentee's exclusive right" and negate the notice function served by the claims. *Id.* at 1054 (quoting *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997)). Application of the disclosure-dedication rule is a question of law and thus is appropriate for summary judgment. *See Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005) (citing *Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1331 (Fed. Cir. 2004)).

In *PSC*, the Federal Circuit considered how specific a disclosure in a written description must be to dedicate matter to the public and held that:

if one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This 'disclosure-dedication' rule does not mean that any generic reference in a written description necessarily dedicates all members of that particular genus to the public. The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.

PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 335 F.3d 1353, 1360 (Fed. Cir. 2004). In other words, the relevant test is whether one of ordinary skill in the art reading the patent could identify a specific, unclaimed alternative and understand that it could be used as a substitute for the claimed matter. This test is met when the patent mentions the alternative in a way that would be understood by one of ordinary skill in the art. See Toro, 383 F.3d at 1334. The disclosure of unclaimed subject matter need not satisfy the written description requirement of 35 U.S.C. § 112. Id.

B. Application to the '055 Patent

The disclosure-dedication rule would preclude CIEA from asserting infringement under the doctrine of equivalents if the '055 Patent disclosed use of the NOD/LtSz-scid mouse as an alternative since it did not claim such use of the NOD/LtSz-scid mouse. The court therefore considers whether the '055 Patent disclosed use of the NOD/LtSz-scid mouse as an alternative such that this unclaimed subject matter would be deemed dedicated to the public. The '055 Patent discusses the NOD/LtSz-scid mouse and how it, like the NOD/Shi-scid mouse, is an ideal strain for creating immunodeficient mice suitable for engraftment of heterologous cells. *See* '055 Patent 1:32-38 ("an NOD/Shi-scid mouse and an NOD/LtSz-scid mouse which exhibit multifunctional immunodeficiency . . . are the most noteworthy as laboratory animals suitable for engraftment of heterologous cells"). The patent also points out that the NOD/LtSz-scid mouse has been backcrossed with other mouse strains in the prior art for this very purpose. *See id.* 1:66-2:13 (backcrossing the NOD/LtSz-scid mouse with a β2m KO mouse to create immunodeficient mice with engraftment capacity). These references suggest to one of ordinary skill in the art that NOD/LtSz-scid mice could be used as an alternative to the NOD/Shi-scid mice called for in the claims.

Indeed, CIEA contended in its claim construction brief and at the *Markman* hearing that a person of ordinary skill in the art reading the patent would understand that any NOD-scid mouse, including a NOD/LtSz-scid mouse, could be used to achieve the patent's stated objective of creating an immunodeficient mouse with engraftment capacity. *See* Dkt. No. 164 Ex. A 117: 3-9 (" . . . as long as the mouse is a NOD mouse, then that is what one of skill in the art would undertake from the disclosures and the patent. They're not going to be concerned with the substrain . . . "); *see also* Dkt. No. 100 at 2, 8, 15.

The disclosure of unclaimed subject matter in the '055 Patent is similar to the disclosure found to trigger the disclosure-dedication rule in *PSC*. The patent in *PSC* claimed an invention for securing a heat sink to a chip using a clip with "an elongated, resilient metal strap." 355 F.3d at 1355. Though the patent limited its claim to metal clips, the written description stated that "other prior art devices use molded plastic and/or metal parts that must be cast or forged which again are more expensive." *Id.* at 1356. The Federal Circuit held that this disclosure that the prior art

included clips with plastic parts placed the public on notice that "plastic had been used as an alternative to metal in the prior art, and that the future use of plastic would therefore not infringe." *Id.* at 1358. Consequently, the patentee had dedicated use of plastic parts to the public and could not assert infringement under the doctrine of equivalents. *Id.* at 1360. As discussed above, the '055 Patent clearly disclosed use of the NOD/LtSz-scid mouse in the prior art. Indeed, the '055 Patent's discussion of how the NOD/LtSz-scid mouse had been used in the prior art is far more extensive than the brief mention of plastic parts in the *PSC* patent. Accordingly, the '055 Patent placed the public on notice that NOD/LtSz-scid mice had been used as an alternative to NOD/Shi-scid mice in the prior art, and future use of NOD/LtSz-scid mice would therefore not infringe. *See PSC*, 355 F.3d at 1358.

Because the '055 Patent discloses but does not claim use of the NOD/LtSz-scid mouse, this unclaimed subject matter is dedicated to the public and cannot be recaptured under the doctrine of equivalents. *See Johnson & Johnston*, 285 F.3d at 1054. Even if the patentee did not intend to dedicate this subject matter to the public, "[t]he patentee, rather than the public, must bear the burden of inadvertent errors in the patent – including inadvertent dedications." *PSC*, 355 F.3d at 1361. Since the disclosure-dedication rule bars CIEA from asserting infringement under the doctrine of equivalents, the court need not reach Jackson's alternative argument that CIEA's doctrine of equivalents position would vitiate the NOD/Shi and NOD/Shi-scid claim limitation in its entirety.

III. ORDER

	For the 1	foregoing r	easons, the	e court	grants	Jackson'	s motion	for sum	ımary ju	dgment	of non-
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DATED: 6/1/10 RONALD M. WHYTE

RONALD M. WHYTE
United States District Judge

CCL

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